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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,303	05/26/2005	Pasqua Anna Oreste	GRT/3687-100	6675

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
4173	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,303	ORESTE ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-89 and 101-114* is/are pending in the application.

4a) Of the above claim(s) *60-89 and 114* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *101-113* is/are rejected.

7)☒ Claim(s) *111* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3 pages/17Dec04, 26May05, 02Oct07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT application PCT/IB03/02339 filed 17 Jun 2003; and claims benefit of foreign priority documents ITALY MI2002 A 001854 filed 27 Aug 2002; ITALY MI2002 A 001346 filed 18 Jun 2002; and ITALY MI2002 A 001345 filed 18 Jun 2002. Claims 60-89 and 101-114 are pending in the current application. Claims 60-78, drawn to a non-elected invention, are withdrawn. Claims 79-89 and 114, drawn to a non-elected species, are withdrawn. Claims 101-113 are examined on the merits herein.

Election/Restrictions

Applicant's election of the invention of Group II, claims 79-89 and 101-114, in the reply filed on 02 Oct 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 60-78 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02 Oct 2007.

Applicant's election of the species of (epi)K5-amine-O-oversulfate-derivative having a free amine in the reply filed on 02 Oct 2007 is acknowledged.

Claims 79-89 and 114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made in the reply filed on 02 Oct 2007.

Claim 114, drawn to a LMW-(epi)K5-N-sulfate, does not read upon the elected species of (epi)K5-amine-O-oversulfate-derivative having a free amine. Therefore Claim 114 is withdrawn.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

The following excerpt of the oath as filed illustrates the error.

Priority Foreign Application(s):

Application Number	Country	Day/Month/Year Filed
MI2002A001345	IT	18 June 2002
MI2002A001346;MI2002A001854	IT	18 June 2002
	IT	27 August 2002

Specification

The abstract of the disclosure is objected to because of minor typographical errors:

Line 1: "(epi)KS-N sulfates", and

Line 3: "Nacyl-(epi)K5-amine-O-oversulfates". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: minor typographical errors such as:

Page 13, lines 8, "lmw-K5-N-sulfate",

Page 13, lines 9, "lmw-K5-amine-O-oversulfated",

Page 13, line 24, "methylic" and "ethylic", and

Page 15, line 20, "lmwepiK5-N-sulfate".

Appropriate correction is required.

Claim Objections

Claim 111 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 111 as disclosed depends from claim 106, which depends from claim 104 and discloses a LMW-epiK5-amine-O-oversulfate with uronic units 20-60% those of iduronic acid. The compound of formular (III'b) as disclosed in claim 111 depicts a LMW-K5-amine-O-oversulfate, with no epimerization at the C5 position. For purposes of furthering prosecution, Examiner has claim 111 has been interpreted as depending from claim 110, paralleling the construction of claims 106 and 107.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 101-103, 108, 112 and 113 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as (epi)K5-amine-O-oversulfate (page 6 ,lines 26-27), which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 101-103, 108, 112 and 113 are directed to encompass (epi)K5-amine-O-oversulfate-**derivatives** which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and because chemical derivatives are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim, and provides no limiting definition for "derivative". A non-limiting definition is provided on page 7, lines 17-19, indicating the suffix "-derivative" includes both derivatives from native K5 and those of a low molecular weight.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description provision of 35 USC § 112, first

paragraph. The species specifically disclosed are not representative of the genus because the genus of "derivatives" is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See Vas-Cath at page 1115.)

The court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when… the evidence indicates ordinary artisans could not predict the operability … of any other species." (see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, an no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 101-107, 112 and 113 are rejected under 35 U.S.C. 102(b) as being anticipated by Oreste et al. (US Patent Application Publication US 2002/0062019,

published 23 May 2002, cited in PTO-892) and explained by Jacobsson et al. (Biochemical Journal, 1979, 179, p77-87, cited in PTO-892).

Oreste et al. discloses a composition comprising epiK5-amine-O-oversulfate in a mixture with a pharmaceutical excipient, ultrafiltered deionized water (page 4, paragraphs 72, lines 6-8), anticipating instant claim 101. Oreste et al. discloses the product, (epi)K5-amine-O-oversulfate, where position 2 of the glucosamine is completely unsulfated (page 5, paragraph 73, lines 3-5), and the reaction disclosed by Oreste et al. on page 4, paragraphs 70-72 is the same as the reaction disclosed in Example 1: EpiK5-amine-O-oversulfate of the instant specification, spanning page 49-50. The composition is obtained as a salt in which the cation is sodium (page 4, paragraph 72, line 3), anticipating instant claim 112. The composition is in the form of a solution (page 4, paragraph 72, line 2-3), anticipating instant claim 113.

Oreste et al. discloses the use of polysaccharide starting materials with a molecular weight of 30,000 D and 5,000 D (page 3, paragraph 51, line 2), anticipating instant claim 102. Oreste et al. discloses the epimerization generates a ratio of iduronic acid/glucuronic acid between 40:60 and 60:40 (page 4, paragraph 68) and a content of sulfates per disaccharide of 2.0-3.5 (page 5, paragraph 73, lines 1-3), anticipating instant claim 103.

Instant claim 104 recites a LMW-epiK5-amine-O-oversulfate in which q is an integer from 2 to 20, with a degree of sulfation from 3.55 to 4, and a 2,5-anhydromannitol unit. The starting material of 5,000 D (page 3, paragraph 51, line 2) is comprised of a disaccharide of uronic acid-N-acetyl-glucosamine that has a molecular

weight of approximately 400 D. Therefore a starting polysaccharide with a molecular weight of 5,000 D subjected to the reaction disclosed by Oreste et al. on page 4, paragraphs 70-72 corresponds to an epiK5-amine-O-oversulfate wherein q, the number of disaccharides, is 12. Oreste et al. does not specifically disclose a degree of sulfation from 3.55 to 4, but because the product of Oreste et al. is produced from same reactant treated with the same reaction conditions as Example 1: EpiK5-amine-O-oversulfate of the instant specification, spanning page 49-50, it should inherently anticipate the characteristics of the instantly claimed epiK5-amine-O-oversulfate. Oreste et al. discloses chemical depolymerization of the polysaccharide to obtain low molecular weight products (page 8, paragraph 121, lines 1-4) and discloses the depolymerization method of reaction with nitrous acid and subsequent reduction with borohydride (page 8, paragraph 123, lines 1-4). Jacobsson et al. explains that the chemical depolymerization of heparin-like polysaccharides by reaction with nitrous acid, HNO_2, and subsequent reduction generates 2,5-anhydromannitol at the reducing end (page 78, left column, lines 14-30). Subjecting the heparin-like polysaccharide of the starting material disclosed by Oreste et al. to the disclosed chemical depolymerization conditions followed by the disclosed sulfation reaction by would inherently create the epiK5-amine-O-oversulfate with the sulfated 2,5-anhydromannitol at the reducing end.

Instant claim 105 recites "wherein, in said chain mixture of formula II', the uronic units are 40-60% consisting of iduronic acid, R is at least 40% SO_3^-, R' and R" are both SO_3^- or one is hydrogen and the other is 5-10% SO_3^- in glucuronic acid and 10-15% SO_3^- in iduronic acid, n is an integer from 3 to 15, with a mean molecular weight from

approximately 4,000 to approximately 8,000." Oreste et al. discloses the position 6 of the glucosamine is sulfated at 80-95% and the position 2 is completely unsulfated, and the other sulfate groups are present in position 3 of the amino sugar, R, and 2 and 3 of the uronic acid, R' and R" respectively (page 5, paragraph 73, lines 3-7). Oreste et al. does not specify the percent of R, R', and R" that is sulfated. However, because the product of Oreste et al. is produced from same reactant treated with the same reaction conditions as Example 1: EpiK5-amine-O-oversulfate of the instant specification, spanning page 49-50, it should inherently anticipate the characteristics of the instantly claimed epiK5-amine-O-oversulfate.

Oreste et al. discloses K5 starting materials with a molecular weight of 1,500 D or 2,000 D (page 7, paragraph 112, lines 1-3). A starting material of 1,500 D is comprised of a disaccharide of uronic acid-N-acetyl-glucosamine that has a molecular weight of approximately 400 D. Therefore a starting polysaccharide with a molecular weight of 1,500 D subjected to the reaction disclosed by Oreste et al. on page 4, paragraphs 70-72 corresponds to an epiK5-amine-O-oversulfate wherein q, the number of disaccharides, is 4 or 5, anticipating instant claims 106 and 107.

Claim 101 and dependent claims 102-107, 112 and 113 recite a product-by-process, an (epi)K5-amine-O-oversulfate-derivative or one of its pharmaceutically acceptable salts "isolated in sodium salt form and optionally transformed into another pharmaceutically acceptable salt". "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the

product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oreste et al. (US Patent Application Publication US 2002/0062019, published 23 May 2002, cited in PTO-892) as explained by Jacobsson et al. (Biochemical Journal, 1979, 179, p77-87, cited in PTO-892) and in view of Naggi et al. (US Patent 6,329,351, issued 11 Dec 2001, cited in PTO-892).

Oreste et al. as explained by Jacobsson et al. discloses a composition comprising epiK5-amine-O-oversulfate in a mixture with a pharmaceutical excipient, ultrafiltered deionized water (page 4, paragraphs 72, lines 6-8) and further characteristics of the epiK5-amine-O-oversulfate, anticipating instant claims 101-107, 112 and 113 as recited above. Oreste et al. discloses K5 starting materials with a molecular weight of 1,500 D or 2,000 D (page 7, paragraph 112, lines 1-3). A starting material of 1,500 D is comprised of a disaccharide of uronic acid-glucosaminesulfate that has a molecular weight of approximately 420 D. Therefore a starting polysaccharide with a molecular weight of 1,500 D subjected to the reaction disclosed by Oreste et al. on page 4, paragraphs 70-72 corresponds to an epiK5-amine-O-oversulfate wherein q, the number of disaccharides, is 4 or 5, anticipating instant claims 106 and 107.

Oreste et al. does not disclose the use of the non-epimerized K5 polysaccharide.

Naggi et al. teaches the deacetylation and subsequent sulfation of K5 polysaccharide (column 1, lines 41-43) to produce the sulfated K5 polysaccharide. Naggi et al. teaches the sulfated K5 polysaccharide using a sulfation reaction performed using the pyridine/sulfur trioxide adduct in dimethylformamide disclosed by Oreste et al. (column 3, lines 42-45) Naggi et al. teaches that the sulfated non-epimerized K5 polysaccharide shows favorable therapeutic activity (column 1, lines 31-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the invention of Oreste et al. with the non-epimerized K5 polysaccharide to produce the K5-amine-O-oversulfate. Elimination of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04 IIA. Elimination of step (c) C5 epimerization, disclosed by Oreste et al. page 4, paragraph 59, to eliminate the epimerization at C5 and practice the invention of Oreste et al. with the non-epimerized K5 polysaccharide to produce the K5-amine-O-oversulfate would have been obvious to one of ordinary skill in the art at the time of the invention. Naggi et al. teaches that the sulfated non-epimerized K5 polysaccharide shows favorable therapeutic activity (column 1, lines 31-39). Therefore one of ordinary skill in the art at the time of the invention would be motivated by the teaching of Naggi et al. to practice the invention of Oreste et al. with the obvious elimination of step (c) C5 epimerization to give the non-epimerized K5-amine-O-oversulfate.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 101 is provisionally rejected on the ground of nonstatutory double patenting over claims 32-35 of copending Application No. 10/582,687. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Instant claim 101 recites, "A pharmaceutical composition including, as an active ingredient, an (epi)K5-amine-O-oversulfate-derivative or one of its pharmaceutically acceptable salts, isolated in sodium salt form and optionally transformed into another pharmaceutically acceptable salt, in mixture with a pharmaceutical excipient."

Claim 32 of copending Application No. 10/582,687 recites, "A pharmaceutical composition comprising, as active ingredient, a pharmacological active amount of an (epi)K5-amine-O-oversulfate-derivative having a sulfation degree of from 2 to 4, or of a pharmaceutically acceptable salt thereof, in admixture with a pharmaceutical carrier."

Claims 33-35 recite the composition of claim 32 as a product-by-process.

The instant application defines "oversulfate" to be a sulfation degree of at least 2.2, rendered obvious by the range of 2 to 4 in copending Application No. 10/582,687. See instant specification page 7, lines 1-4.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was

rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Claims 101-107 are provisionally rejected on the ground of nonstatutory double patenting over claims 110-116 and 134 of copending Application No. 10/518,302. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The instant claims 101-107 are drawn to composition comprising epiK5-amine-O-oversulfate in a mixture with a pharmaceutical excipient. Claims 110-116 and 134 of copending Application No. 10/518,302 are drawn to the epiK5-amine-O-oversulfate. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the compound epiK5-amine-O-oversulfate claimed in copending Application No. 10/518,302 with a pharmaceutical excipient such as ultrafiltered deionized water.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSL

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614